

REMARKS

Claims 1 – 14 have been canceled without prejudice. Applicants do reserve the right to claim the canceled subject matter in a continuation or a divisional.

New claims 15 to 23 have been entered. Support for these new claims can be found throughout the specification. More in particular, new claim 15 finds support in former claim 14 and page 4, line 6 of the specification.

Claim 16 is supported by canceled claim 2. Claim 17 is supported by canceled claim 3. Claim 18 is supported by canceled claim 4. Claim 19 is supported by page 7, line 12 of the specification. Claim 20 is supported by canceled claim 7. Claim 21 is supported by canceled claim 8. Claim 22 is supported by canceled claim 9. Claim 23 is supported by canceled claim 10.

Claim rejections – 35 USC §112, first paragraph

Applicants submit that by entering new claims, the rejection under 35 USC §112, first paragraph has been obviated.

Claim rejections – 35 USC §112, second paragraph

Applicants submit that by entering new claims, the rejection under 35 USC §112, second paragraph has been obviated.

Double patenting

Applicants submit that by entering new claims, the obviousness type double patenting rejection has been obviated.

Claim rejections – 35 USC §103

Applicants submit that in the present invention the erythropoietin is essentially contained in the interstitial fluid. The Examiner's attention is respectfully directed to the passage on page 4, lines 19 to 26:

“In accordance with the present invention, it has been discovered that, quite unexpectedly, the liposomal EPO compositions prepared under the mild conditions described herein exhibit improved stability, i.e. the liposomes themselves are stable and at the same time the chemical degradation and aggregation of the biologically effective substance is minimized. As a further unexpected advantage, the EPO active ingredient does not adhere to the surface of the vial container or IV tubing even though the EPO is not substantially incorporated within the liposomes, but instead essentially contained in the interstitial fluid as a liposomal formulation.” [emphasis added]

In other words in the formulation according to the present invention, the EPO is actually present in the aqueous layer outside the liposomes. A small percentage of the EPO is actually bound to the surface but most of the EPO is not linked even to the surface of the liposomes.

The *Maitani et al.* reference teaches formulations wherein a high percentage of the EPO is actually inside the liposomes. The *Collins* reference teaches formulations wherein EPO is attached to the outer surface of the liposomes.

Applicants submit that one ordinary skill in the art cannot find it obvious to combine a teaching of EPO within the liposomes (*Maitani et al*) with a teaching of liposomes having EPO attached to the outer surface of the liposomes (*Collins*) and arrive at the formulation of the present invention wherein the EPO is neither in nor for the most part attached to the outer surface, but actually essentially contained in the interstitial fluid, i.e. the fluid that separates one liposome from another.

Applicants contend JP 0823417 also discloses EPO that is within the liposomes. The Examiner's attention is drawn towards line 20 of the text of the abstract : "...to give Epo enclosed in SS-liposome or SG-liposome." Again, Applicants submit that it would not be obvious for a person skilled in the art to combine a reference that discloses liposomes with EPO inside with a reference disclosing liposomes with EPO attached to the surface and arrive at the present invention, that teaches EPO that is mainly in the interstitial fluid.

Applicants submit that the dependent claims from new claim 15 have to be novel and non obvious in view of the novelty and the non obviousness of independent claim 15.

Early favorable action on the merits is respectfully requested.

Please charge any deficiency or credit any over-payment to Deposit Account Number 10-0750/CCS0202CNT/FDC.

Applicants respectfully request that a timely Notice of Allowance be issued in this case of pending claims 15-23.

Respectfully submitted,

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